



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to polydextrose and changes in bowel function (ID 784), changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 784), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 785) and reduction of gastro-intestinal discomfort (ID 784) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to polydextrose and changes in bowel function (ID 784), changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 784), decreasing potentially pathogenic gastro-intestinal microorganisms (ID 785) and reduction of gastro-intestinal discomfort (ID 784) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to polydextrose and changes in bowel function, changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract, decreasing potentially pathogenic gastro-intestinal microorganisms and reduction of gastro-intestinal discomfort. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is polydextrose. The Panel considers that polydextrose is sufficiently characterised in relation to the claimed effects.

Changes in bowel function

The claimed effect is “improves the bowel function”. The target population is assumed to be the general population. The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk or softer stools may be a beneficial physiological effect, provided these changes do not result in diarrhoea.

¹ On request from the European Commission, Question No EFSA-Q-2008-1571, EFSA-Q-2008-1572, adopted on 25 March 2011.

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³ Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Gut/Immune: Jean-Louis Bresson, Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Yolanda Sanz, Stephan Strobel, Daniel Tomé and Hendrik van Loveren.

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No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and changes in bowel function.

Changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract

The claimed effect is “improves the bowel function”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel notes that the claimed effect refers to changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract. The Panel considers that changes in SCFA production and/or pH in the gastro-intestinal tract are not beneficial physiological effects *per se*, but need to be linked to a beneficial physiological or clinical outcome. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and a beneficial physiological effect related to changes in SCFA production and/or pH in the gastro-intestinal tract.

Decreasing potentially pathogenic gastro-intestinal microorganisms

The claimed effect is “prebiotic/bifidogenic”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to increasing numbers of bacteria which are considered to be “beneficial”. The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect. The Panel considers that the claimed effect, in the context of decreasing potentially pathogenic gastro-intestinal microorganisms, might be a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and decreasing potentially pathogenic gastro-intestinal microorganisms.

Reduction of gastro-intestinal discomfort

The claimed effect is “improves the bowel function”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to reducing gastro-intestinal discomfort. The Panel considers that reduction of gastro-intestinal discomfort is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and reduction of gastro-intestinal discomfort.

KEY WORDS

Polydextrose, bowel function, potentially pathogenic gastro-intestinal microorganisms, SCFA production, gastro-intestinal discomfort, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

See Appendix B

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is polydextrose.

Polydextrose is produced by the poly-condensation of glucose in the presence of sorbitol and citric acid under vacuum at high temperatures (Radosta et al., 1992). Polydextrose is highly branched, with a degree of polymerisation between 2 and 110 (on average approximately 12 glucose units), and with an average molecular weight of ~2,000 Daltons (Allingham, 1982; Murray, 1988). All possible linkages with the glycosidic carbon of glucose are present: α - and β -1,2; 1,3; 1,4; and 1,6; with the 1,6 linkage predominating (Auerbach et al., 2007). Polydextrose is highly soluble in water (80 g/100 g at 25°C) leading to a low viscosity solution (Allingham, 1982; Auerbach et al., 2007). Besides the polymer, polydextrose consists of small amounts of the starting materials glucose, sorbitol and citric acid, as well as levoglucosan and hydroxymethylfurfural formed by caramelisation during the poly-condensation process. Owing to the complex linkage distribution in the highly branched structure, it has been stated that polydextrose is resistant to gastric acid and mammalian gastro-intestinal enzymes (Auerbach et al., 2006). Polydextrose is used primarily in the food industry as a stabiliser, thickening agent, humectant and carrier (E1200).

The Panel considers that the food constituent, polydextrose, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Changes in bowel function (ID 784)

The claimed effect is “improves the bowel function”. The Panel assumes that the target population is the general population.

The Panel notes that the claimed effect refers to changes in bowel function.

The Panel considers that changes in bowel function, such as reduced transit time, more frequent bowel movements, increased faecal bulk or softer stools, may be a beneficial physiological effect, provided these changes do not result in diarrhoea.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

⁵ EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

2.2. Changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 784)

The claimed effect is “improves the bowel function”. The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract.

The Panel considers that changes in SCFA production and/or pH in the gastro-intestinal tract are not beneficial physiological effects *per se*, but need to be linked to a beneficial physiological or clinical outcome. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and a beneficial physiological effect related to changes in SCFA production and/or pH in the gastro-intestinal tract.

2.3. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 785)

The claimed effect is “prebiotic/bifidogenic”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to increasing numbers of bacteria which are considered to be “beneficial”.

The numbers/proportions of bacterial groups that would constitute a “beneficial/healthy/good/or natural balance” of gastro-intestinal flora have not been established. Increasing the number of any group of microorganisms, including lactobacilli and/or bifidobacteria, is not in itself considered to be a beneficial physiological effect.

The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect.

The Panel considers that the claimed effect, in the context of decreasing potentially pathogenic gastro-intestinal microorganisms, might be a beneficial physiological effect.

2.4. Reduction of gastro-intestinal discomfort (ID 784)

The claimed effect is “improves the bowel function”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effect refers to reducing gastro-intestinal discomfort.

The Panel considers that reduction of gastro-intestinal discomfort is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Changes in bowel function (ID 784)

The references provided for the scientific substantiation of the claim included textbooks and general reviews which did not provide original data for the scientific substantiation of the claim. The majority of human, animal and *in vitro* studies were unrelated to the food constituent which is the subject of the health claim, and/or were unrelated to the claimed effect. Studies which were unrelated to the claimed effect included references on the effect of polydextrose consumption on blood lipids, intestinal

microbiota and glucose absorption, and on the energy value of polydextrose. One paper was in Japanese and a translation into an EU language was not available to the Panel. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

In four of the human intervention studies provided, the effect of polydextrose consumption on bowel function was evaluated.

In a randomised, placebo-controlled, double-blind parallel study, the effect of polydextrose (0, 4, 8 or 12 g/day given for 28 days) added to the usual diet on faecal frequency and faecal wet and dry weight in 120 healthy volunteers (66 men and 54 women; 30 subjects per group) was investigated (Zhong et al., 2000). The Dunnett's multiple pair-wise comparison test was used to assess differences between the polydextrose groups and the placebo group. The Panel notes that the study has several weaknesses: the substance used as placebo was not specified, compliance to the diet during the intervention was not reported, and no details about randomisation or blinding were given. In addition, the main outcome of the study was not specified, no information about power calculations was provided, and multiplicity of outcome measures was not adequately taken into consideration in the statistical analyses. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Endo et al. (1991), in a sequential non-randomised intervention study, evaluated faecal weight in eight healthy volunteers (six male) given a low cholesterol diet, a high cholesterol diet, and a high cholesterol diet supplemented with polydextrose (15 g/day) consecutively for two weeks each. The Panel notes that the order of the interventions was not randomised, and notes the lack of information about the methods used for statistical analysis. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Tomlin and Read (1988) assessed the effect of polydextrose consumed in addition to the usual diet on transit time, stool mass, stool frequency and stool consistency in a group of 12 healthy male volunteers in a randomised, single-blind, three arm cross-over study. After a 10 day run-in period, subjects received 30 g/day of polydextrose, 7 g/day of psyllium, and a mixture of polydextrose and psyllium (30 and 2 g/day, respectively) for 10 days each with a one week wash-out period in between. The statistical significance of differences between periods was tested by the Wilcoxon's matched-pairs signed ranks test. The Panel notes that the study was not adequately controlled, and that the dose of polydextrose used was several times higher than in the proposed conditions of use. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The effect of "acute" polydextrose ingestion (days 9-16, 30 g/day) and "chronic" polydextrose ingestion (days 17-38, 30 g/day) compared to the "control" period without polydextrose consumption (days 1-8, 0 g/day) on gastro-intestinal transit time and faecal weight was evaluated by Achour et al. (1994) in a non-randomised sequential study in seven male volunteers on a controlled diet. The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of polydextrose consumption on changes in bowel function in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and changes in bowel function.

3.2. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 785)

The references provided for the scientific substantiation of the claim included textbooks and general reviews which did not provide original data for the scientific substantiation of the claim. The majority of human, animal and *in vitro* studies were unrelated to the food constituent which is the subject of the health claim, and/or were unrelated to the claimed effect. Studies which were unrelated to the claimed effect included references on the energy value of polydextrose, and on the effects of polydextrose consumption on cyclo-oxygenase-2 gene expression in mucosa, on gastro-intestinal transit time and on breath hydrogen production. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two human studies focused on the effects of polydextrose on faecal bifidobacteria and other microorganisms (e.g. lactobacilli, *Bacteroidaceae*, *Bacteroides fragilis*, *Bacteroides vulgaris*, *Bacteroides intermedius*, *Eubacterium*, *Peptococcaeae*, *Veilonella*, *Megasphaera*, *Enterobacteriaceae*, streptococci, lecithinase-negative clostridia and yeasts) (Endo et al., 1991; Jie et al., 2000). The Panel notes that the microorganisms assessed in these studies are part of the commensal intestinal microbiota, and that the studies did not provide evidence for the characterisation of any of these groups as pathogens. In one human study, the effect of polydextrose on *Clostridium perfringens* was investigated (Endo et al., 1991), but no information was given about the pathogenicity of the bacterial strains studied.

The Panel notes that no human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim. The Panel considers that evidence provided in animal studies is not sufficient to predict the occurrence of an effect of polydextrose consumption on decreasing potentially pathogenic gastro-intestinal microorganisms in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and decreasing potentially pathogenic gastro-intestinal microorganisms.

3.3. Reduction of gastro-intestinal discomfort (ID 784)

The references described in section 3.1 were also provided in relation to this claimed effect.

No human studies were provided which addressed outcomes related to gastro-intestinal discomfort.

The Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and reduction of gastro-intestinal discomfort.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, polydextrose, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

Changes in bowel function (ID 784)

- The claimed effect is “improves the bowel function”. The target population is assumed to be the general population. Changes in bowel function, such as reduced transit time, more frequent bowel movements, increased faecal bulk or softer stools, may be a beneficial physiological effect, provided these changes do not result in diarrhoea.
- A cause and effect relationship has not been established between the consumption of polydextrose and changes in bowel function.

Changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract (ID 784)

- The claimed effect is “improves the bowel function”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is assumed that the claimed effect refers to changes in short chain fatty acid (SCFA) production and/or pH in the gastro-intestinal tract. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of polydextrose and a beneficial physiological effect related to changes in SCFA production and/or pH in the gastro-intestinal tract.

Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 785)

- The claimed effect is “prebiotic/bifidogenic”. The target population is assumed to be the general population. Decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of polydextrose and decreasing potentially pathogenic gastro-intestinal microorganisms.

Reduction of gastro-intestinal discomfort (ID 784)

- The claimed effect is “improves the bowel function”. The target population is assumed to be the general population. In the context of the proposed wordings and the clarifications provided by Member States, it is assumed that the claimed effect refers to reducing gastro-intestinal discomfort. Reduction of gastro-intestinal discomfort is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of polydextrose and reduction of gastro-intestinal discomfort.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1571, EFSA-Q-2008-1572). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

REFERENCES

- Achour L, Flourié B, Briet F, Pellier P, Marteau P and Rambaud JC, 1994. Gastrointestinal effects and energy value of polydextrose in healthy nonobese men. *American Journal of Clinical Nutrition*, 59, 1362-1368.
- Allingham RP, 1982. Polydextrose - A new food ingredient. In: *Chemistry of Foods and Beverages: Recent Developments*. Eds Charalambous G, Inglett G. Academic Press, New York, 293-303.
- Auerbach M, Craig S and Mitchel H, 2006. Bulking agents: Multifunctional ingredients. In: *Sweeteners and Sugar Alternatives in Food Technology*. Ed Mitchell H. Blackwell Publishing Ltd, Oxford.
- Auerbach MH, Craig SA, Howlett JF and Hayes KC, 2007. Caloric availability of polydextrose. *Nutrition Reviews*, 65, 544-549.

- Endo K, Kumemura M, Nakamura K, Fujisawa T, Suzuki K, Benno Y and Mitsuoka T, 1991. Effect of high cholesterol diet and polydextrose supplementation on the microflora, bacterial enzyme activity, putrefactive products, volatile fatty acid (VFA) profile, weight, and pH of the feces in healthy volunteers. *Bifidobacteria and Microflora*, 10, 53–64.
- Jie Z, Bang-Yao L, Ming-Jie X, Hai-Wei L, Zu-Kang Z, Ting-Song W and Craig SA, 2000. Studies on the effects of polydextrose intake on physiologic functions in Chinese people. *American Journal of Clinical Nutrition*, 72, 1503-1509.
- Murray P, 1988. Polydextrose. In: *Low-calorie products*. Eds Birch GG, Lindley MG. Elsevier Applied Science, London and New York, 83-100.
- Radosta S, Boczek P and Grossklaus R, 1992. Composition of Polydextrose® Before and After Intestinal Degradation in Rats. *Starch*, 44, 150-153.
- Tomlin J and Read NW, 1988. A comparative study of the effects on colon function caused by feeding ispaghula husk and polydextrose. *Alimentary Pharmacology and Therapeutics*, 2, 513-519.
- Zhong J, Luo B-y, Xiang M-j, Liu H-w, Zhai Z-k, Wang T-s and Stuart AC, 2000. Studies on the effects of polydextrose intake on physiologic functions in Chinese people. *American Journal of Clinical Nutrition*, 72, 1503-1509.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

⁶ OJ L12, 18/01/2007

⁷ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁸ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B**EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to polydextrose, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
784	Polydextrose	<p>Improves the bowel function</p> <p><u>Clarification from MS:</u></p> <p>Improved intestinal conditions (reduces colonic pH, increase SCFA production) and intestinal functions (such as stool consistency and ease of defecation)</p> <ul style="list-style-type: none"> - Polydextrose helps to improve intestinal regularity - Polydextrose helps to promote a healthy bowel - Polydextrose helps to improve gut comfort - Polydextrose promotes improved intestinal conditions (reduces colonic pH, increase SCFA production) and intestinal functions (such as stool consistency and ease of defecation) - Polydextrose promotes improved bowel function - Polydextrose improves bowel function and gut comfort 	<ul style="list-style-type: none"> - polydextrose promotes good intestinal health; -polydextrose improves bowel function and gut comfort;
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Amount of consumption: 8 g/Tag - Amount of consumption: 5 bis 10 Gramm (g) - Other condition: Sonden- und Trinknahrungen. - Amount of consumption: 8 g/Tag. Other condition: beginnt bei 8g/Tag. - Beverage and bakery industry products and dairy products with 4-12g/serving of polydextrose. - Bakery products and dairy products with 10g/serving of lactitol and 4-12g/serving of polydextrose. Use of lactitol in beverages is not allowed. According to the respondent, lactitol and polydextrose are highly stable and endure the processing well. - 4g/day - Where a daily value is indicated the amount per serving is typically 25% unless otherwise stated. 4g/ day. 		
ID	Food or Food constituent	Health Relationship	Proposed wording
785	Polydextrose	Prebiotic / Bifidogenic	<ul style="list-style-type: none"> -prebiotic - polydextrose stimulate the growth of beneficial bacteria

			<p>in the gut;</p> <ul style="list-style-type: none"> - polydextrose stimulates the growth of Bifidobacteria in the colon; - polydextrose stimulate the growth of Lactobacilli bacteria in the gut; - prebiotics promote healthy/well-balanced gut flora
	<p>Conditions of use</p> <ul style="list-style-type: none"> - 4 g/day - Where a daily value is indicated the amount per serving is typically 25% unless otherwise stated. 4g/ day - 4 g pro Tag 		

GLOSSARY AND ABBREVIATIONS

SD	Standard deviation
SCFA	Short chain fatty acid